What Is Claimed Is:

Claim 1. A medical device comprising:

a biocompatible structure carrying a genetic material, said biocompatible structure comprising a polymeric coating that coats at least a portion of said structure, said genetic material comprising:

(a) a first therapeutic agent comprising a vector containing a first polynucleotide that establishes a gene expression sufficient to produce a therapeutically sufficient amount of one or more products encoded by said first polynucleotide; and

(b) a second therapeutic agent comprising at least one of (i) a second polynucleotide carried by a carrier; (ii) a protein; (iii) a non-genetic therapeutic agent, or (iv) cells.

Claim 2. The medical device of claim 1, wherein said second therapeutic agent is said second polynucleotide, said vector establishes a delayed gene expression, and said carrier establishes an early gene expression.

Claim 3. The medical device of claim 1, wherein said vector is an adenoassociated virus vector.

Claim 4. The medical device of claim 1, wherein said carrier is a viral vector, plasmid vector, non-plasmid vector, or a combination thereof.

Claim 5. The medical device of claim 1, wherein said carrier comprises a naked nucleic acid molecule.

Claim 6. The medical device of claim 4, wherein said non-plasmid vector comprises

liposomes, lipofectin, lipoplexes, polyplexes, dextrans, starburst, dendrimer conjugates, polybenrene dimethyl sulfoxide, protamine sulfate, antibody conjugates, polylysine conjugates, gramacidin S, artificial conjugates, viral envelopes, viral-like particles, nano or micro particles, or a combination thereof.

Claim 7. The medical device of claim 1, wherein said first polynucleotide and said second polynucleotide are the same.

Claim 8. The medical device of claim 1, wherein said vector, said carrier, or both are site specific.

Claim 9. The medical device of claim 1, wherein said first polynucleotide, said second polynucleotide, or both encodes one or more products selected from the group consisting of: nitric oxide synthase; human fibroblast growth factor; vascular endothelial growth factor; tissue plasminogen activator; anti-thrombogenic agents; erythropoietin; antioxidants; angiogenic and anti-angiogenic agents; agents blocking smooth muscle cell proliferation; angiopeptin; monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents; calcium entry blockers; antineoplastic/antiproliferative/ anti-mitotic agents; anti-coagulants; antithrombin compounds; platelet receptor antagonists; anti-thrombin antibodies; anti-platelet receptor antibodies; prostaglandin inhibitors; platelet inhibitors; vascular cell growth promotors; transcriptional activators; translational promotors; vascular cell growth inhibitors; growth factor receptor antagonists; transcriptional repressors; translational repressors; or replication inhibitors.

Claim 10. The medical device of claim 1, wherein said vector comprises a viral

vector.

Claim 11. The medical device of claim 10, wherein said vector is thermostable, replication-deficient, non-immunogenic, or a combination thereof.

Claim 12. The medical device of claim 1 wherein said expression is achieved in about 20% to about 80% of cells exposed to said genetic material.

Claim 13. The medical device of claim 2, wherein said delayed expression is an expression delayed from about two days to about three weeks after administration *in vivo*.

Claim14. The medical device of claim 1, wherein said vector, said carrier, or both contain regulatory sequences.

Claim 15. The medical device of claim 1, wherein said cells comprise transfected, transformed or transduced cells.

Claim 16. The medical device of claim 15, wherein said cells are autologous cells.

Claim 17. The medical device of claim 1, wherein said biocompatible coating comprises polyurethane, silicone, EVA, poly-l-lactic acid /poly ε-caprolactone blends, or a combination thereof.

Claim 18. The medical device of claim 1, wherein said polymer coating is from about 1 to about 40 layers having a thickness of from about 1 to about 10 μm/ layer of coating.

Claim19. The medical device of claim 1, wherein said structure is a stent.

Claim 20. The medical device of claim 19, wherein said stent is a metallic stent.

Claim 21. The medical device of claim19, wherein said stent is a coil spring made from aliphatic polyester blends.

Claim 22. The medical device of claim 19, wherein said stent is a microporous tube

made from aliphatic polyester blends.

Claim 23. The medical device of claim 1, wherein said first therapeutic agent and said second therapeutic agent are applied onto or impregnated into a same layer of said polymer coating.

Claim 24. A method of inhibiting or treating restenosis in a patient, said method comprising administering at a predetermined site within the body of said patient the device of claim 1.

Claim 25. The method of claim 23, wherein said site is a site of mechanical injury to an arterial wall produced by treatment of an atherosclerotic lesion by angioplasty.

Claim 26. A method of controlled delivery of a genetic material to a mammalian body comprising;

(A) applying a polymer coating to at least a portion of a medical device;

(B) applying a genetic material to said polymer coating to obtain a genetically coated medical device, said genetic material comprising: (a) a first therapeutic agent comprising a vector containing a first polynucleotide that establishes a gene expression sufficient to produce a therapeutically sufficient amount of one or more products encoded by said first polynucleotide; and (b) a second therapeutic agent comprising at least one of (i) a second polynucleotide carried by a carrier; (ii) a protein; (iii) a non-genetic therapeutic agent; or (iv) cells; and

(C) inserting or implanting said genetically coated medical device at a predetermined site in said mammal.

Claim 27. The method of claim 26, wherein said vector is adenoassociated virus

vector.

Claim 28. The method of claim 26, wherein said carrier is a viral vector, plasmid vector, a non-plasmid vector, or a combination thereof.

Claim 29. The method of claim 26, wherein said carrier comprises a naked nucleic acid molecule.

Claim 30. The method of claim 26, wherein said non-plasmid vector comprises liposomes, lipofectin, lipoplexes, polyplexes, dextrans, starburst, dendrimer conjugates, polybenrene dimethyl sulfoxide, protamine sulfate, antibody conjugates, polylysine conjugates, gramacidin S, artificial conjugates, viral envelopes, viral-like particles, nano or micro particles, or a combination thereof.

Claim 31. The method of claim 26, wherein said first polynucleotide and said second polynucleotide are the same.

Claim 32. The method of claim 26, wherein said vector, said carrier, or both are site specific.

Claim 33. The method of claim 26, wherein said first therapeutic agent, said second therapeutic agent, or both cause the production of one or more products selected from the group consisting of: nitric oxide synthase; human fibroblast growth factor; vascular endothelial growth factor; tissue plasminogen activator; anti-thrombogenic agents; erythropoietin; antioxidants; angiogenic and anti-angiogenic agents; agents blocking smooth muscle cell proliferation; angiopeptin; monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents; calcium entry blockers; antineoplastic/antiproliferative/ anti-mitotic agents; anti-coagulants; antithrombin

compounds; platelet receptor antagonists; anti-thrombin antibodies; anti-platelet receptor antibodies; prostaglandin inhibitors; platelet inhibitors; vascular cell growth promotors; transcriptional activators; translational promotors; vascular cell growth inhibitors; growth factor receptor antagonists; transcriptional repressors; translational repressors; replication inhibitors, or a combination thereof.

Claim 34. The method of claim 26, wherein said vector comprises a viral vector.

Claim 35. The method of claim 34, wherein said viral vector is thermostable, replication-deficient, non-immunogenic, or a combination thereof.

Claim 36. The method of claim 26, wherein said expression is achieved in about 20% to about 80% of cells exposed to said genetic material.

Claim 37. The method of claim 26, wherein said vector is a delayed expression vector and said carrier is an early expression carrier.

Claim 38. The method of claim 37, wherein said delayed expression is an expression delayed from about two days to about 3 weeks after administration in vivo.

Claim 39. The method of claim 26, wherein said vector, said carrier, or both contain regulatory sequences.

Claim 40. The method of claim 26, wherein said cells comprise transfected, transformed or transduced cells.

Claim 41. The method of claim 40, wherein said cells are autologous cells.

Claim 42. The method of claim 26, wherein said coating comprises polyurethane, silicone, EVA, poly-l-lactic acid /poly ε-caprolactone blends, or a combination thereof.

Claim 43. The method of claim 26, wherein said polymer coating is from about 1 to

about 40 layers having a thickness of from about 1 to about 10 μm/ layer of coating.

Claim 44. The method of claim 26, wherein said structure is a stent.

Claim 45. The method of claim 44, wherein said stent is a coil spring made from aliphatic polyester blends.

Claim 46. The method of claim 44, wherein said stent is a microporous tube made from aliphatic polyester blends.

Claim 47. The method of claim 44, wherein said stent is a metallic stent.

Claim 48. The method of claim 26, wherein said first therapeutic agent and said second therapeutic agent are applied onto or impregnated into a same layer of said polymer coating.

Claim 49. The method of claim 26, wherein said therapeutic agent is a protein.

Claim 50. The method of claim 26, wherein said therapeutic agent is a small molecule.

Claim 51. The method of claim 26, wherein said therapeutic agent is a non-protein based agent.